(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY MINUTES OF AD HOC COMMITTEE ON INSPECTION PROCESS

May 17, 2010 Commonwealth Conference Center 9960 Mayland Drive Henrico, Virginia 23233 Hearing Room 3

CALL TO ORDER: A working meeting of an ad hoc committee of the Board of

> Pharmacy was called to order at 10:25am for the purpose of discussing the inspection process regarding sterile and non-

Perimeter Center

sterile compounding.

PRESIDING: Jennifer H. Edwards, Committee Chairman

MEMBERS PRESENT: Bobby Ison

Gill B. Abernathy

STAFF PRESENT: Elizabeth Scott Russell, Executive Director

Caroline D. Juran, Deputy Executive Director

Sammy Johnson, Assistant Director of Enforcement

DISCUSSION: The committee continued discussions regarding the Board's

piloting of a new inspection process wherein an inspector may issue at the conclusion of a routine inspection a modified consent order imposing monetary penalties when the on-site inspection discloses certain violations of law or regulation. The committee reviewed and amended the major deficiency, as it was listed in guidance document 110-9, regarding the monitoring of refrigerator and freezer temperatures and also recommended language for a new minor deficiency for this Additionally, the committee reviewed USP requirement. Chapters 795 and 797 regarding non-sterile and sterile compounding identified areas inspection. and for Recommendations for major and minor deficiencies regarding these subjects were also established, along with corresponding monetary penalties. The committees recommendations will be presented to the full Board for review at the next full Board

meeting to be held June 2, 2010.

ADJOURN: The meeting adjourned at 2:30 p.m.

Elizabeth Scott Russell **Executive Director**

Jennifer H. Edwards, Chairman

Date